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EXAMINER

CROUCH, DEBORAH

ART UNIT PAPER NUMBER

1632

DATE MAILED: 03/31/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/845,353

Applicant(s)

STICE ET AL.

Examiner

Deborah Crouch, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 21 February 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1,3,5-17,19,20,22-24,27-35,47-62,65-77 and 79-101 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3,5-17,19,20,22-24,27-35,47-62,65-77 and 79-101 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121:

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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Applicant's arguments filed February 21, 2003 in paper no. 8 have been fully considered but they are not persuasive. The amendment has been entered. Claims 1, 3, 5-17, 19, 20, 22-24, 27-35, 47-62, 65-77, and 79-101 are pending.

The terminal disclaimer filed on February 21, 2003 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S Patents 5,945,577, 6,215,041, 6,235,969 and 6,235,970 B1 has been reviewed and is accepted. The terminal disclaimer has been recorded. The terminal disclaimer overcomes the rejection of the claims under the judicially created doctrine of obviousness-type double patenting made in the previous office action.

Applicant's amendments to claims 1 and 61 has overcome the rejection made in the previous office action under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3, 5-17, 24, 29,30, 32, 34, 47, 48, 50, 52, 54, 55, 57, 59, 61, 62, 79-93, 96, 99 and 100 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of cloning a pig comprising inserting a desired differentiated pig cell or cell nucleus into an enucleated pig oocyte to form a nuclear transfer unit, activating the nuclear transfer agent, and *transferring multiple nuclear transfer units or additional pig embryos into the uterus of a female pig* and permitting the nuclear transfer unit to develop into a pig, does not reasonably provide enablement for transferring one nuclear transfer unit into the uterus of pig recipient for reasons set for the in the previous office action. The specification does not enable any person skilled in the art to which it pertains,

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or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

At the time of filing, it was well recognized in the art, that in nuclear transfer procedures, female pigs required the development of at least four fetuses to maintain pregnancy (Prather, page 1886, parag. 2, lines 1-4). This is a critical step to the production of either pigs or pig fetuses and must be included in the claims.

Applicant argues that the specification addresses the problem of relating to producing a cloned embryo capable of being implanted and developing into a cloned or full term pig. Applicant argues that persons skilled in the art would know that in transferred cloned NT units into a female, it should be transferred together with several additional embryos to obtain successful development. Applicant argues it is unfairly limiting for them to state that several NT units are implanted into the pig uterus. These arguments are persuasive in part.

Applicant should note that the claim has been amended to state multiple NT units or an NT unit with additional pig embryos. The intention is that the implantation of multiple pig embryos is critical to the implementation of the claim. This is stated in Prather. Applicant has not provided arguments or evidence that Prather's teaching is incorrect. For enablement, non-critical elements can be omitted from the claim, but elements critical to the claim must be included. For now, the transfer of the NT unit(s) with addition pig embryos, is essential for the enablement of the claim.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 29,47,48,50,52,54,55,57,59-65 and 78 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claims 29,47,48,50,52,54,55,57 and 59 are confusing because claim 29 is written as a method of producing a CICM cell line. Claims 47,48,50,52,54,55,57 and 59 read as if they are methods of producing chimeric embryos, fetuses, progeny and offspring. In particular, chimeric fetuses, progeny and offspring do not have the embryonic structure of an inner cell mass.

Applicant argues that the metes and bounds of these claims are clear. This argument is not persuasive. The production of cloned pigs is a separate invention from methods of producing CICM cells. The outcome of the claim has no relation to the preamble. It is not clear if these claims are methods of making CICM cells or methods of cloning pigs.

Claim 60 is vague as it states "desired differentiated pig CICM cell." All somatic and germ cells would fall into this category. Thus, claims 61-65 are the same scope as claims 1, 2, 5, 18 and 19. Therefore, applicant is advised that should claims 1,2,5,18 and 19 be found allowable, claims 61-65 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

There was no reply to this rejection.

19,20,22-,23,27,28,31,33, 35, 49, 51, 53, 56, 58, 60, 65-77, 94, 95, 97, 98, 101

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 19, 20, 27, 28, 65, 66, 68, 70-75, 94, 98 and 101 remain rejected under 35 U.S.C. 102(b) as being clearly anticipated by Cisneros et al (1996) J. Animal Science 74, 925-933 for reasons set forth in the previous office action.

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Cisneros et al teach a commercial pig breed, BCH, and a three breed cross, HYD, (page 926, col. 1, parag. 1, lines 4-6).

Claims 18,26 and 64 remain rejected under 35 U.S.C. 102(b) as being clearly anticipate by Cukrowska et al (1996) Immunology 87, 487-492 for reasons set forth in the previous office action.

Cukrowska et al teach Minnesota Miniature pig fetuses (page 488, col. 1, parag. 2, lines 1-3).

Claims 21-23, 67, 76, 77 and 95 remain rejected under 35 U.S.C. 102(b) as being clearly anticipated by Fodor et al (1994) Proc. Natl. Acad. Sci. 91, 11153-11157 for reasons set forth in the previous office action.

Fodor et al teach the production of transgenic pigs which express a cDNA sequence encoding human CD59 (page 11155, figure 2). The pigs disclosed by Fodor et al are offspring and progeny of founder pigs (page 11154, col. 1, parag. 2, lines 2-4).

Claim 31 remains rejected under 35 U.S.C. 102(b) as being clearly anticipated by Strojek et al (1990) Theriogenology 33, 901-913 for reasons set forth in the previous office action.

Strojek et al teach the culture of ICM cells as cell lines 6-10 (page 903, parag. 5, lines 1-5 and page 907, figure 2).

Claim 35 remains rejected under 35 U.S.C. 102(b) as being clearly anticipated by Brameld et al (1995) J. Endocrin. 146, 239-245 for reasons set forth in the previous office action.

Brameld et al teaches differentiated pig hepatocytes (page 240, col. 1, parag. 2 to col. 2, through parag. 1).

Claims 49, 51, 53 and 97 remain rejected under 35 U.S.C. 102(b) as being clearly anticipated by Onishi et al (1994) Biology of Reproduction 51, 1069-1075 for reasons set forth in the previous office action.

Onishi et al teach pig chimeras which result from crosses between Chinese pigs and European pigs (page 1071, figure 2). These pigs are chimeric offspring and progeny of the crosses.

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Claims 56, 58, 60 and 69 remain rejected under 35 U.S.C. 102(b) as being clearly anticipated by Rosengard et al (1995) Transplantation 59, 1325-1333 for reasons set forth in the previous office action.

Rosengard et al teach pigs, which have had a desired DNA inserted, are germ line mosaics for the DNA sequence encoding human DAF (page 1326, col. 1, parag. 1, lines 4-10). These pigs are deemed to be chimeric as some of the cells of pig contained the transgene and others did not.

Applicant argues that the products of the claims are not anticipated by the art as the products produced by the claimed method contain allogenic mitochondria and the those of the art do not. This argument is not persuasive.

Applicant has not provided any supporting evidence that a cloned pig will always contain allogenic mitochondria. The mitochondria of the pig are the pig's mitochondria. It cannot be allogenic. Allogenic means that the mitochondria would be from another pig. The examiner believes that applicant is arguing that the pigs made by the method claimed contain the mitochondria of the oocyte donor rather than the mitochondria of the nuclear donor. However, applicant has offered no evidence that this is indeed the case, or that an pig made by nuclear transfer would only and always have the mitochondria of the oocyte donor. Further, there is no evidence that the variety of mitochondria in pigs is so vast that it is impossible for the oocyte donor and the nuclear donor to have the same mitochondrial genotype. Further, at what level of mitochondrial genotype is applicant referring. A base-by-base analysis, an RFLP analysis or some other analysis. Further, to overcome the art, distinguishing features need to be in the claims.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 33 remains rejected under 35 U.S.C. 103(a) as being unpatentable over Strojek et al (1990) Theriogenology 33, 901-913 for reasons of record.

Strojek et al teach the culture of ICM cells as cell lines 6-10 (page 903, parag. 5, lines 1-5 and page 907, figure 2). Strojek et al also teach that ICM cells can be transformed to provide a method for producing transgenic livestock since pronuclear injection of livestock embryos has lead only to limited successes (page 902, lines 5-11).

Applicant argues that the products of the claims are not obvious in view of the cited art as the product produced by the claimed method contain allogenic mitochondria and the those of the art do not. This argument is not persuasive.

Applicant has not provided any supporting evidence that a cloned pig will always contain allogenic mitochondria. The mitochondria of the pig are the pig's mitochondria. It cannot be allogenic. Allogenic means that the mitochondria would be from another pig. The examiner believes that applicant is arguing that the pigs made by the method claimed contain the mitochondria of the oocyte donor rather than the mitochondria of the nuclear donor. However, applicant has offered no evidence that this is indeed the case, or that an pig made by nuclear transfer would only and always have the mitochondria of the oocyte donor. Further, there is no evidence that the variety of mitochondria in pigs is so vast that it is impossible for the oocyte donor and the nuclear donor to have the same mitochondrial genotype. Further, at what level of mitochondrial genotype is applicant referring. A base-by-base analysis, an RFLP analysis or some other analysis. Further, to overcome the art, distinguishing features need to be in the claims. (This is a repeat of the response to applicant's rebuttal of the 102(b) rejections.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date




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of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Crouch, Ph.D. whose telephone number is 703-308-1126. The examiner can normally be reached on M-Th, 8:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah J. Reynolds can be reached on 703-305-4051. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

  
Deborah Crouch, Ph.D.  
Primary Examiner  
Art Unit 1632

dc  
March 28, 2003